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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,661	11/06/1998	BRET A. SHIRLEY	5784-3	3329
27476	7590	03/18/2004		
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER KAM, CHIH MIN	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/187,661

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,13,16-20 and 28-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3, 4, 13, 16-20 and 28-50 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 3, 4, 13, 16-20 and 28-50 are pending.

Applicants' amendment filed December 29, 2003 is acknowledged, and applicants' response has been fully considered. Claims 19, 38-41 and 44 have been amended, and new claims 48-50 have been added, thus claims 1, 3, 4, 13, 16-20 and 28-50 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 19, 38-41 and 44, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment of the claim, and applicants' response at page 6 in the amendment filed December 29, 2003.

Claim Objections

3. Claims 19, 39, 41 and 44 are objected to because of the use of the term "poly(D,L-lactide-co-glycolide", where one parenthesis ")" is missing.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3, 4, 13, 16-20 and 28-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-48 and 85-112 of copending Application No. 09/188,051. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 4, 13, 16-20 and 28-50 in the instant application disclose a low salt-containing aqueous composition comprising biologically active human IGF-I or a functional variant thereof in a concentration of about 250 mg/ml and a pH about 5.0 or greater, wherein the variant has at least 80% sequence identity to human IGF-I. This is obvious in view of claims 29-48 and 85-112 in the copending application which disclose a composition having a pH of 5.5 or greater, comprising IGF-I or a biologically active analog thereof having at least 70% sequence identity to human IGF-I at a concentration of about 12 mg/ml to about 200 mg/ml, and at a temperature of about 4 °C, and a solubilizing compound comprising a guanidinium group, wherein the solubilizing compound is in an amount sufficient to make IGF-I or analog thereof soluble. Since the low salt-containing composition can be a composition containing a salt such as arginine or other arginine compounds in an amount that makes IGF-1 or its analog more soluble at higher concentration and at about 4 °C, and the concentration of IGF-1 is about 250 mg/ml, thus, both sets of claims encompass a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of about 250 mg/ml and a pH about 5.5 or greater, wherein the variant has at least 80% sequence identity to human IGF-I. Thus, claims 1, 3, 4, 13, 16-20 and 28-50 in present application and claims 29-48 and 85-112 in the copending application are obvious variations of a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of about 250 mg/ml and a

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pH about 5.5 or greater, wherein the amount of arginine compound makes IGF-I or its analog more soluble at about 4 °C.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate they continue to traverse the rejection for the reasons of record, however, they will consider the propriety of filing a Terminal Disclaimer when subject matter is considered allowable in this application or in the 09/188,051 application. The response has been considered, however the statement is not persuasive because the claims cannot be allowed when the rejection maintains. A notice of allowance for application 09/188,051 was mailed on February 9, 2004.

Conclusion

5. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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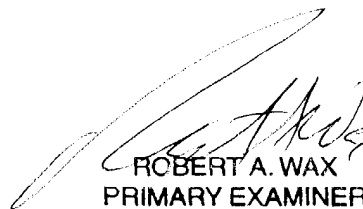
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 13, 2004


ROBERT A. WAX
PRIMARY EXAMINER